K001711

JUN 2 0 2000

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Steve Singlar
Regulatory Approvals Engineer
Agilent Technologies
3000 Minuteman Road, MS 0135
Andover, MA 01810
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This summary was prepared on May 10, 2000.

2. This premarket notification describes modifications to the ImagePoint Hx M2410B system. It includes addition of Intraoperative indication for use (K990339) and Trapezoidal Imaging (K944048) to the operating platform. It adds the 21390A(K990339) for Intraoperative use to the platform. The classification names for these devices are:

90 ITX - Diagnostic Ultrasound Transducer
90 IYO - Ultrasonic Pulsed Echo Imaging System
90 IYN - Ultrasonic Pulsed Doppler Imaging System.

3. The M2410B ImagePoint Hx system, with new platform modes, new indications for use, and new transducer, functions in the same way as its predicate devices, the M2410A (K954028) and M2410B (K990400) and M2424A (K990339) by allowing ultrasound imaging of the human anatomy.

4. The subject platform and transducer have the same functionality and intended uses as their predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2000

Agilent Technologies, Inc.
C/O Carole Stamp
Responsible Third Party Official
510(k) Program Manager
TUV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K001711
Trade Name: M2410B ImagePoint HX Multispecialty System, Version B.1
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Dated: June 2, 2000
Received: June 5, 2000

Dear Ms. Stamp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the M2410B ImagePoint HX Multispecialty System, Version B.1, as described in your premarket notification:

Transducer Model Number

21390A

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

## Diagnostic Ultrasound Indications for Use Form

510(k) Number: K 001711
Device Name: M2410B ImagePoint Hx Ultrasound System
Intended Use: Diagnostic Ultrasound Imaging and Doppler Analysis of the human body as follows:

| | MODE OF OPERATION | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (harmonic imaging) |
| Ophthalmic | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Fetal | NA | P | P | P | NA | P | P | NA | P | P |
| Abdominal | NA | P | P | P | NA | P | P | NA | P | P |
| Intraoperative | NA | N | N | N | NA | N | N | NA | N | NA |
| Intraoperative Neurological | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Pediatric | NA | P | P | P | P | P | P | NA | P | P |
| Small Parts [1] (small organ) | NA | P | P | P | NA | P | P | NA | P | NA |
| Neonatal Cephalic | NA | P | P | P | NA | P | P | NA | P | NA |
| Adult Cephalic | NA | P | P | P | NA | P | P | NA | P | P |
| Cardiac | NA | P | P | P | P | P | P | NA | P | P |
| Transesophageal | NA | P | P | P | P | P | P | NA | P | NA |
| Transrectal | NA | P | P | P | NA | P | P | NA | P | NA |
| Transurethral | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Transvaginal | NA | P | P | P | NA | P | P | NA | P | NA |
| Intravascular | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Peripheral Vascular | NA | P | P | P | NA | P | P | NA | P | NA |
| Laparoscopic | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Musculo-skeletal Conventional | NA | P | P | NA | NA | NA | NA | NA | NA | NA |
| Musculo-skeletal Superficial | NA | P | P | NA | NA | NA | NA | NA | NA | NA |
| Other | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |

N = new indication; P = previously cleared by FDA; E = added under Appendix F.
Additional Comments: Other indications or modes: Combined modes are B+Color, B+Angio, B+PW, M+Color are available in all applications as noted.
Combined mode of B+PW+Color (known as Triplex) is available on all applications EXCEPT Cardiac and Transesophageal.
[1]Small Parts: breast, scrotum and thyroid.
Previously cleared submissions for this platform: K990400, K972348, K954028

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

David A. Seltzman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001711

## Diagnostic Ultrasound Indications for Use Form

510(k) Number: K001711
Device Name: Transducer 21390A on the M2410B
Intended Use: Diagnostic Ultrasound Imaging and Doppler Analysis of the human body as follows:

| | MODE OF OPERATION | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Power Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Fetal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Abdominal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Intraoperative | NA | N | N | N | NA | N | N | NA | N | NA |
| Intraoperative Neurological | NA | N | N | N | NA | N | N | NA | N | NA |
| Pediatric | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Small Parts (small organ) | NA | N | N | N | NA | N | N | NA | N | NA |
| Neonatal Cephalic | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Adult Cephalic | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Cardiac | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Transesophageal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Transrectal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Transvaginal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Transurethral | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Intravascular | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Peripheral Vascular | NA | N | N | N | NA | N | N | NA | N | NA |
| Laparoscopic | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Musculo-skeletal Conventional | NA | N | N | N | NA | N | N | NA | N | NA |
| Musculo-skeletal Superficial | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Other (specify) | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |

N = new indication; P = previously cleared by FDA; E = added under Appendix E.
Additional Comments: Combined modes are: B+Color, B+Angio, B+PW, M+Color and, B+PW+Color (known as Triplex), are available in all 21390A applications as noted.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001711